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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,745	10/17/2003	Knut Meyer	CL2314 US NA	3903

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EXAMINER	
FRONDA, CHRISTIAN L	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,745	MEYER ET AL.	
	Examiner	Art Unit	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-24 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 17 October 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/18/2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-24 are pending and under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 5 the phrase "represented by SEQ ID NO: 30" renders the claim vague and indefinite. The metes and bounds of the claim are unclear since it is not certain if applicants are actually referring to SEQ ID NO: 30 for the recited HCHL expression cassette. Amending the claim to recite the phrase "wherein the HCHL expression cassette is SEQ ID NO: 30" may overcome the rejection.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the evaluation of the claims for compliance with the written description requirement of 35 U.S.C. 112, of particular relevance is 66 FR 1099, Friday, January 5, 2001,which states:

> "*Eli Lilly* explains that a chemical compound's name does not necessarily convey a written description of the named chemical compound, particularly when a genus of compounds is claimed. *Eli Lilly,* 119 F.3d at 1568, 43 USPQ2d at 1405. The name, if it does no more than distinguish the claimed genus from all others by function, does not satisfy the written description requirement because "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. *Eli Lilly,* 119 F.3d at 1568, 43 USPQ2d at 1406. Thus *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed." (see p. 1100, 1st column, line 47 to 2nd column, line 2).

The claims are drawn to a method comprising the use of a genus of nucleic acids encoding a 4-hydroxycinnamoyl-CoA hydratase/lyase (HCHL) expression cassette, a genus of nucleic acids encoding HCHLs, a genus of tissue specific promoters from any nucleic acid encoding any protein involved in cellulose synthesis, and a genus of nucleic acid molecules encoding para-hydroxybenzoic acid UDP-glucosyltransferases. The scope of each genus includes many members with widely differing structural, chemical, and physiochemical properties including widely differing nucleotide or amino acid sequences. Furthermore, each genus is highly variable because a significant number of structural differences between genus members exist.

The specification discloses an HCHL expression cassette of SEQ ID NO: 30 (Example 3); a tissue specific promoter of SEQ ID NOs: 26, 43, 44, 45, 46, 49, 81, 82, or 83 (Examples 4, 6-9); a nucleic acid molecule encoding a 4-hydroxycinnamoyl-CoA hydratase/lyase (HCHL) of SEQ ID NOs: 5, 6, 58, 59, 60, 61, 62, 63, or 64 (Examples 1-2 , 8, and 9); and para-hydroxybenzoic acid UDP-glucosyltransferase of SEQ ID NOs: 65, 66, or 67. However, the specification does not describe and define any structural features and nucleotide or amino acid sequences commonly possessed by members of each genus. Furthermore, recitation of "HCHL expression cassette", "HCHL", "tissue-specific promoter", and "para-hydroxybenzoic acid UDP-glucosyltransferase" do not define any structural features and nucleotide or amino acid sequences commonly possessed by each genus. Thus, one skilled in the art cannot predict and visualize or recognize the identity of the members of each genus for use in the claimed method.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a

precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v, Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. Therefore, the instant claims are not adequately described.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of a genus of nucleic acids encoding a HCHL expression cassette, a genus of nucleic acids encoding HCHLs, a genus of tissue specific promoters from any nucleic acid encoding any protein involved in cellulose synthesis, and a genus of nucleic acid molecules encoding para-hydroxybenzoic acid UDP-glucosyltransferases for use in the claimed method to selectively produce para-hydroxybenzoic acid in plant stem tissue.

The claims are additionally rejected for the following reasons. The claims encompass tissue specific promoters and any gene encoding para-hydroxybenzoic acid UDP-glucosyltransferase. Gene elements which are not particularly described, including promoter regions, regulatory elements, and untranslated regions, are essential to the function of the claimed invention since the claims recite "tissue-specific promoter" and "gene encoding a para-hydroxybenzoic acid UDP-glucosyltransferase". The art indicates that the structure of these gene elements are empirically determined. Therefore, the structure of these elements which applicants considers as being essential to the function of the claim are not conventional in the art.

There is no known or disclosed correlation between the coding region of a polynucleotide encoding a para-hydroxybenzoic acid UDP-glucosyltransferase and the structure of the non-described promoter regions, regulatory elements, and untranslated regions. In view of the above considerations, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of any gene encoding a para-hydroxybenzoic acid UDP-glucosyltransferase and any tissue-specific promoter. Amending the claims to recite the specific SEQ ID NO of the promoter and reciting a polynucleotide encoding para-hydroxybenzoic acid UDP-glucosyltransferase of a specific SEQ ID NO may overcome the rejection.

6. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method to selectively produce para-hydroxybenzoic acid in plant stem tissue using a plant comprising a 4-hydroxycinnamoyl-CoA hydratase/lyase (HCHL) expression cassette of SEQ ID NO: 30; or a plant comprising a nucleic acid molecule encoding a 4-hydroxycinnamoyl-CoA hydratase/lyase (HCHL) of SEQ ID NOs: 5, 6, 58, 59, 60, 61, 62, 63, or 64; a tissue specific promoter of SEQ ID NOs: 26, 43, 44, 45, 46, 49, 81, 82, or 83; and a nucleic acid molecule encoding a para-hydroxybenzoic acid UDP-glucosyltransferase of SEQ ID NOs: 65, 66, or 67; does not reasonably provide enablement for any other embodiment as recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any method to selectively produce para-hydroxybenzoic acid in plant stem tissue using any plant comprising any nucleic acid encoding any HCHL expression cassette; or any plant comprising any nucleic acid molecule encoding any HCHL of any amino acid sequence and biological source, any tissue specific promoter from any nucleic acid encoding any protein involved in cellulose synthesis, and any nucleic acid molecule encoding any para-hydroxybenzoic acid UDP-glucosyltransferase of any amino acid sequence and biological source.

The specification provides guidance and working examples for an HCHL expression cassette of SEQ ID NO: 30 (Example 3); a tissue specific promoter of SEQ ID NOs: 26, 43, 44, 45, 46, 49, 81, 82, or 83 (Examples 4, 6-9); a nucleic acid molecule encoding a 4-hydroxycinnamoyl-CoA hydratase/lyase (HCHL) of SEQ ID NOs: 5, 6, 58, 59, 60, 61, 62, 63, or 64 (Examples 1-2 , 8, and 9); and para-hydroxybenzoic acid UDP-glucosyltransferase of SEQ ID NOs: 65, 66, or 67.

However, the specification does not provide guidance, prediction, and working examples for any nucleic acid encoding any HCHL expression cassette of any nucleotide sequence, any nucleic acid molecule encoding any HCHL of any amino acid sequence and biological source, any tissue specific promoter from any nucleic acid encoding any protein involved in cellulose synthesis, and any nucleic acid molecule encoding any para-hydroxybenzoic acid UDP-glucosyltransferase of any amino acid sequence and biological source.

Thus, an undue amount of trial and error experimentation must be preformed where such experimentation involves searching and screening for any HCHL expression cassettes, any nucleic acid molecule encoding any HCHL of any amino acid sequence and biological source, any tissue specific promoter of any nucleic acid for expression isolated from any protein involved in cellulose synthesis, and any nucleic acid molecule encoding any para-hydroxybenzoic acid UDP-glucosyltransferase. A vast number of biological sources must be searched and screened for each of the nucleic acids encoding HCHL, para-hydroxybenzoic acid UDP-glucosyltransferase, and tissue specific promoter and their respective nucleotide sequences determined. Trial and error experimentation must then be performed to ascertain whether transforming a plant with the said nucleic acids will enable the plant to produce para-hydroxybenzoic acid only in the plant stem tissue. General teaching regarding screening and searching for the claimed invention is not guidance for making the claimed invention.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific SEQ ID NO of the nucleic acid molecules encoding each of HCHL, para-hydroxybenzoic acid UDP-glucosyltransferase, and tissue specific promoter, where transformation of a plant with these nucleic acid molecules results in a plant that can produce para-hydroxybenzoic acid in plant stem tissue. Without such a guidance, the amount of experimentation left to those skilled in the art to make the invention is undue and well outside of routine experimentation.

Conclusion

7. No claim is allowed.

8. The following reference made of record and not relied upon is considered pertinent to applicant's disclosure: Viitanen et al. (Plant Physiol. 2004 Dec;136(4):4048-60. Epub 2004 Nov 24) teach the advantage of integrating the *Escherichia coli* ubiC gene that codes for chorismate pyruvate-lyase into the tobacco chloroplast genome in that chorismate becomes a readily available plant precursor for p-hydroxybenzoic acid biosynthesis.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N

Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

TEKCHAND SAIDHA
PRIMARY EXAMINER